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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JULIANNA LISZIEWICZ and
FRANCO LORI

Appeal 2010-000027
Application 10/081,922
Technology Center 1600

Decided: April 20, 2010

Before FRANCISCO C. PRATS, MELANIE L. McCOLLUM, and JEFFREY N. FREDMAN, *Administrative Patent Judges.*

Opinion filed for the Board by *Administrative Patent Judge* FREDMAN.

Opinion dissenting-in-part filed by *Administrative Patent Judge* McCOLLUM.

FREDMAN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to methods of transfecting antigen presenting cells by applying the complex to skin or

mucosal surfaces. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

Statement of the Case

Background

"Expression of foreign genes in antigen presenting cells (APC) may be used to generate efficient CTL [cytotoxic T lymphocyte] response in animals. Therefore, gene transfer and genetic modification of APC has potential to generate effective vaccine and therapeutic approaches against different diseases, including viral infections and cancer." (Spec. 4, ll. 7-11.)

The Claims

Claims 23-26, 28, 30-32, 35, 40, 41, 43 and 44 are on appeal[1]. Claims 23, 26, and 30 are representative and read as follows:

> 23. A method of transfecting antigen presenting cells, the steps comprising selecting a gene delivery complex that transfects antigen presenting cells, comprising DNA and a sugar, or polyethylenimine, or polyethylenimine derivative, and administering the complex by applying the complex without the use of a needle to the skin or mucosa surfaces of an animal, wherein said DNA comprises a nucleic acid sequence encoding at least one immunogenic protein operatively linked to a promoter, and whereby antigen presenting cells of said skin or mucosa are transfected.
>
> 26. The method of Claim 25, wherein the derivative is mannosylated polyethylenimine.

[1] The Examiner has withdrawn the provisional double patenting rejection and the new matter rejection, so that currently pending claims 33 and 42 are not subject to any rejection.

30. The method of Claim 26, wherein the complex comprises a 5:1 ratio of mannosylated polyethylenimine nitrogen per DNA phosphate.

The prior art

The Examiner relies on the following prior art references to show unpatentability:

Holler et al.	US 5,908,923	Jun. 1, 1999
Behr et al.	US 6,013,240	Jan. 11, 2000

Liu et al., *Topical application of HIV DNA vaccine with cytokine-expression plasmids induces strong antigen-specific immune responses*, 20 VACCINE 42-48 (2002).

Mittal et al., *Pathology and immunogenicity in the cotton rat (Sigmodon hispidus) model after infection with a bovine adenovirus type 3 recombinant virus expressing the firefly luciferase gene*, 77 J. GEN. VIROLOGY 1-9 (1996) Abstract Only.

Janis Kuby, *Immunology* 8-9 (1992).

The issues

A. The Examiner rejected claim 30 under 35 U.S.C. § 112, second paragraph as being indefinite (Ans. 5).

B. The Examiner rejected claims 23-26, 28, 30-32, 35, 40, 41, 43, and 44 under 35 U.S.C. § 102(e) as anticipated by Behr as evidenced by Liu, Mittal, and Kuby (Ans. 5-7).

C. The Examiner rejected claims 23-26, 28, 30-32, 35, 40, 41, 43, and 44 under 35 U.S.C. § 103(a) as obvious over Behr, Liu, Mittal, Kuby, and Holler (Ans. 7-10).

A. 35 U.S.C. § 112, second paragraph

The Examiner finds that it "is unclear what applicants consider a mannosylated polyethylenimine nitrogen and how such nitrogens are distinguished from polyethylenimine nitrogen." (Ans. 5.) The Examiner finds that Claim 30 "does not clearly first limit the complex to having mannosylated polyethylenimine; therefore, limiting the complex to having a 5:1 ratio of mannosylated PEI nitrogen per DNA phosphate without first limiting the complex to one having mannosylated PEI does not make sense because the complex can made with sugar" (Ans. 5).

Appellants argue that support for the claim is found in the Specification at page 22 (*see* App. Br. 9).

In view of these conflicting positions, we frame the indefiniteness issue before us as follows:

Does the evidence of record support the Examiner's conclusion that claim 30 is indefinite?

Findings of Fact (FF)

1. The Specification teaches that:

> We found that, with PEI-man-DNA complexes, less DNA is required to neutralize PEI-man compared to PEI. Gel electrophoresis experiments using different N:P ratio of PEI-DNA complexes demonstrated that 5:1 (N:P) of PEI-man:DNA complex has neutral charge, in contrast to 3:1 (N:P) PEI-DNA complex. {The neutralization of PEI with the DNA depends on the N(nitrogen):P(phosphate) ratio; one microgram DNA = 3 x 109 molar P and 1 mM PEI = 109 molar N/microliter. This means for example that 10:1 ratio is the mixture of 3microliter 10mM PEI and 1 microgram DNA.

(Spec. 22, ll. 9-16.)

Principles of Law

The test for definiteness under 35 U.S.C. § 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986) (citations omitted).

Analysis

We are not persuaded by the Examiner's rejection. Whether the polyethylenimine is mannosylated or not will not change the location or presence of the nitrogen atoms present on the polyethylenimine, since mannose is a sugar which does not contain nitrogen. The Specification clearly describes how to compare the nitrogen to phosphate ratio (*see* FF 1). In light of this description in the Specification (FF 1), we conclude that the ordinary artisan would have been easily able to calculate the ratio of nitrogen to oxygen for polyethylenimine, whether mannosylated or not.

We also disagree with the Examiner's finding that claim 30 "does not clearly first limit the complex to having mannosylated polyethylenimine" (Ans. 5). Claim 30 requires that "the complex comprises a 5:1 ratio of mannosylated polyethylenimine nitrogen per DNA phosphate" (Claim 30). We conclude that this is a clear and unambiguous requirement for mannosylated polyethylenimine in the complex.

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that claim 30 is indefinite.

B. 35 U.S.C. § 102(e) over Behr

The Examiner finds that "Behr taught a complex comprising i) PEI, and ii) plasmid DNA comprising a nucleic acid sequence encoding luciferase operatively linked to a promoter suspended in 5% glucose" (Ans. 6). The Examiner finds that "Behr taught administering any complex of the invention to the skin or mucosa of an animal" (*id.*). The Examiner finds that "applying a gene delivery complex topically as described by Behr inherently results in transfecting APCs as supported by Liu" (*id.*). The Examiner finds that luciferase "is an immunogenic protein" (*id.*).

Appellants argue that Behr "does not disclose the transfection of antigen presenting cells, or the targeting of antigen presenting cells, a most significant subset of cells, and prominent by its omission" (App. Br. 20). Appellants argue that Behr does not teach "any in vivo method of delivery except injection" (*id.*). Appellants also argue that Liu "is not citeable as prior art against the present claims, which have an admitted priority date of September 15, 1998" (*id.* at 21).

Appellants argue that the "inherency argument by the Examiner is contradicted by the experiments in the Behr reference: Luciferase was used in those experiments and neither undesired immunogenicity or toxicity was found" (*id.* at 33). Appellants argue that "[e]xample 14 of the Behr reference shows failure of one set of materials used successfully in the

claimed method. In order for the Behr reference to be predictive to the level required by an inherency rejection, that transfection with DNA and sugar injected into neural tissue would have had to have worked" (*id.*).

In view of these conflicting positions, we frame the anticipation issue before us as follows:

Does the evidence of record support the Examiner's conclusion that Behr, as evidenced by Liu, Mittal, and Kuby, anticipates the claimed invention?

Findings of Fact

2. Behr teaches that "the pharmaceutical compositions of the invention contain a vehicle which is pharmaceutically acceptable . . . for a topical administration (to skin and/or mucosa)" (Behr, col. 6, ll. 5-9).

3. Behr teaches and claims a "composition comprising at least one nucleic acid and a cationic polymer" (Behr, col. 13, ll. 34-35; claim 1 of Behr).

4. Behr teaches that the "nucleic acid can also contain one or more genes coding for an antigenic peptide capable of generating an immune response in man or animals" (Behr, col. 3, ll. 57-59).

5. Behr teaches that the "peptides include, in particular, antigenic peptides specific to the Epstein Barr virus, the HIV virus, the hepatitis B . . . or the pseudorabies virus, or alternatively tumor-specific peptides" (Behr, col. 3, ll. 63-66).

6. Behr teaches that "30 µg of plasmid pCMV-luc . . . were diluted in 22.5 µl of sterile 5% glucose . . ., 8.5 µl of 100 mM PEI800K . . . were then added. The composition thereby obtained hence contains 9 equivalents

of amines relative to phosphates" (Behr, col. 12, ll. 53-58 (Example 14)). Examples 1 through 12 also describe using plasmids as the nucleic acid vector (*id.* at cols. 7-11).

7. Behr teaches and claims a composition "wherein the polymer is selected from the group consisting of polyethylenimine (PEI) and polyproylenimine (PPI)" (Behr, col. 13, ll. 59-61; claim 4 of Behr).

8. Behr teaches and claims a composition "wherein the polymer amines to nucleic acid phosphates ratio is between 0.5 and 50" (Behr, col. 13, ll. 65-67; claim 6 of Behr).

9. Behr teaches and claims a "composition according to claim 1, comprising a vehicle which is pharmaceutically acceptable for application to the skin and/or the mucosae" (Behr, col. 16, ll. 14-17; claim 33 of Behr).

10. Liu teaches a "method of topical application that relies on the elimination of the keratinocyte layers has made it easier for DNA plasmids to be taken up by antigen-presenting cells in mice, although a gentle modification of the method will be necessary for use in human patients" (Liu 43, col. 1).

11. Liu teaches that "Fan et al. have reported that painting DNA vaccine twice (without stripping) induced an antibody response to HBs antigen and enhanced the lymphoproliferative response. Although painting twice without stripping yielded a marked immune response, stronger immunigenicity, more efficiently achieved, is desirable" (Liu 47, col. 1).

12. Liu teaches that "S-100 immunoreactivity is characteristic of mature DC cells that are effective in antigen presentation" (Liu 47, col. 1).

13. Liu teaches that "stripped skin sections showed more S-100 protein staining and neutrophil-like cell infiltration was greater and more frequently observed (Fig. 3d) than that without stripping (Fig. 3b). These suggested that the stripping facilitated the passage of DNA vaccine through the skin and the uptake of plasmids by antigen expressing cells" (Liu 47, col. 1).

14. Mittal teaches that "[a]ntibodies to both BAd3 and luciferase were detected in sera collected from BAd3-Luc-infected animals until at least 6 weeks p.i. [post infection]" (Mittal abstract).

Principles of Law

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

"It is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." *In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1349 (Fed. Cir. 2002). *See, e.g., MEHL/Biophile Int'l Corp. v. Milgraum,* 192 F.3d 1362, 1365 (Fed. Cir. 1999) ("Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.")

Once a prima facie case of anticipation has been established, the burden shifts to the Appellant to prove that the prior art product does not necessarily or inherently possess the characteristics of the claimed product. *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) ("Where, as here, the claimed

and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product."). *See also In re Spada*, 911 F.2d 705, 708-09 (Fed. Cir. 1990).

A publication dated after an applicant's filing date is acceptable as evidence of characteristics of prior art products. *In re Wilson*, 311 F.2d 266, 268-269 (CCPA 1962) ("The board considered that the publication was properly cited to show a state of fact. After reading the entire publication, so do we. It [is] clearly a discussion of the properties of polyurethane foam products generally, products made by the processes of the prior art of record in this case.... As evidence of the characteristics of prior art foam products, however, we know of no reason in law why it is not acceptable."); *In re Langer*, 503 F.2d 1380, 1391 (CCPA 1974) ("the references relied on by the examiner and the board are not cited as 'prior art' references. Indeed, the effective date, for prior art purposes, of many of these references is subsequent to appellant's earliest filing date. Rather, these references are properly cited for the purpose of showing a fact under the principle of *In re Wilson* ...").

Analysis

Claims 23 and 44

Behr teaches methods of transfecting cells with DNA and polyethylenimine (PEI) (FF 2-3, 7). Behr teaches administering the complex topically (i.e., without a needle) to skin or mucosa surfaces (FF 9). Behr

teaches that the DNA may comprise a nucleic acid sequence which encodes an immunogenic protein (FF 4-5).

Appellants argue that Behr "does not disclose the transfection of antigen presenting cells, or the targeting of antigen presenting cells, a most significant subset of cells, and prominent by its omission" (App. Br. 20).

While Behr does not expressly teach that topical administration will result in transfection of antigen presenting cells, Liu evidences that topical administration will inherently result in transfection of antigen presenting cells (FF 10-13). In particular Liu demonstrates that a "method of topical application that relies on the elimination of the keratinocyte layers has made it easier for DNA plasmids to be taken up by antigen-presenting cells in mice" (Liu 43, col. 1 FF 10). Liu therefore teaches that even topical administration without the keratinocyte elimination step results in uptake of DNA plasmids by antigen-presenting cells and demonstrates this uptake in S-100 cells without the keratinocyte elimination step in figure 3b (FF 13).

The Examiner has therefore provided significant evidence which supports the conclusion that topical administration of skin with DNA will transfect antigen presenting cells. Consequently, under *Best*, the burden of proving that the topical administration of Behr does not inherently satisfy the claims is placed on Appellants. *See In re Best*, 562 F.2d at 1255 ("Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.").

Appellants respond to the citation of Liu by arguing that Liu "is not citeable as prior art against the present claims, which have an admitted priority date of September 15, 1998" (App. Br. 21). This argument is not persuasive because post-filing evidence can be relied on to show the properties inherent in a prior art teaching. *See In re Wilson*, 311 F.2d at 268-69.

Appellants argue that Behr does not teach "any in vivo method of delivery except injection" (App. Br. 20). We are not persuaded. Behr expressly teaches "topical administration (to skin and/or mucosa)" (Behr, col. 6, ll. 8-9; FF 2). Behr claims a "composition according to claim 1, comprising a vehicle which is pharmaceutically acceptable for application to the skin and/or the mucosae" (Behr, col. 16, ll. 14-17; claim 33 of Behr; FF 9). These are in vivo methods of delivery which are topical and do not require injection (FF 2, 9).

Appellants argue that the "inherency argument by the Examiner is contradicted by the experiments in the Behr reference: Luciferase was used in those experiments and neither undesired immunogenicity or toxicity was found" (App. Br. 33). We find this argument unpersuasive because Example 14 does not disclose administration to skin or mucosa, as described in the portions of Behr cited by the Examiner, and because the argument is contradicted by the evidence of Mittal.

When Behr tested a luciferase transfection construct in Example 14, Behr applied the construct to brains of newborn mice for 48 hours (*see* Behr, col. 12, ll. 45-67). Given that Example 14 did not administer the construct to skin or mucosa, immunogenic response would not necessarily be expected

to occur. Further, not only does Mittal demonstrate that luciferase is immunogenic when expressed in lungs after four days (Mittal Abstract, FF 14), but Behr satisfies the requirement in claim 23 for an immunogenic protein directly, without the necessity of demonstrating that luciferase is immunogenic (FF 4-5).

Appellants argue that "[e]xample 14 of the Behr reference shows failure of one set of materials used successfully in the claimed method. In order for the Behr reference to be predictive to the level required by an inherency rejection, that transfection with DNA and sugar injected into neural tissue would have had to have worked" (App. Br. 33).

We are not persuaded because Example 14 of Behr demonstrated that "the compositions enable the plasmid to be transferred efficiently into the brain of mice, whereas no significant luciferase activity is observed when the transfer is carried out by means of the plasmid alone" (Behr, col. 13, ll. 7-10). Thus, Behr demonstrates that when the nucleic acid (plasmid) is combined with PEI and glucose, as required by the claim, the nucleic acid is successfully transfected. This does not demonstrate failure, but rather success.

Claims 24-26 and 30-32

Appellants argue that Behr "does not disclose that glucose and PEI derivatives could be used in the claimed method" (App. Br. 20). Appellants also argue that Behr does not teach "that the glucose solution can be preferred for targeting antigen presenting cells (Claim 31), or that the range of glucose concentration in a method targeting antigen presenting cells is

higher than that disclosed for general use for transfecting neurons in the Behr reference (Claims 32 and 33)" (App. Br. 20).

The Examiner finds that Behr "taught a complex comprising i) PEI, and ii) plasmid DNA . . . suspended in 5% glucose" (Ans. 6). We note that the Examiner has withdrawn the rejection regarding Claim 33 (*see* Ans. 7).

We are not persuaded regarding the use of glucose in Claims 24 and 31-32 because Behr teaches the use of glucose in a composition "used for intracerebral injections" (Behr, col. 12, ll. 59-60) and not for topical use.

As stated in *Arkley*, an anticipatory reference under 35 U.S.C. § 102

> . . . must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. Such picking and choosing may be entirely proper in the making of a 103, obviousness rejection, where the applicant must be afforded an opportunity to rebut with objective evidence any inference of obviousness which may arise from the similarity of the subject matter which he claims to the prior art, but it has no place in the making of a 102, anticipation rejection.

In re Arkley, 455 F.2d 586, 587-588 (CCPA 1972).

The instant situation is similar to *Arkley*, where the instant rejection is a § 102, anticipation rejection which would require picking and choosing glucose from intracerebral injection with a composition for topical application from unrelated parts of the reference in order to arrive at the claimed invention. We are therefore constrained to reverse this rejection.

Claim 43

Appellants argue that Behr does not teach that "use of a sugar-modified polyethylenimine would be desirable (Claim 43)" (*id.* at 21).

The Examiner responds that "[c]laims 25, 26 and 43 are included because they are not limited to a compound that is mannosylated PEI[;] . . . claims 25, 26 and 43 encompass non-sugar-modified PEI solubilized in glucose as in parent claim 24" (Ans. 7).

We find that Appellants have the better position. In our opinion, Claim 43 clearly requires the inclusion of a sugar-modified polyethylenimine into the DNA complex. The Examiner has not identified, nor do we find, any teaching of a sugar-modified polyethylenimine in Behr.

Claim 28

Appellants argue that Behr does not teach "manipulation of electrostatically neutral complexes to target antigen presenting cells (Claim 28)" (App. Br. 20).

We are not persuaded because Behr teaches a composition "wherein the polymer amines to nucleic acid phosphates ratio is between 0.5 and 50" (Behr, col. 13, ll. 65-67; claim 6 of Behr; FF 8). Also, the Examiner finds that "Behr taught that between 5-20 equivalents of PEI amines are used relative to one DNA phosphate (col 8, lines 15-19). The instant specification teaches that the ratio of 5:1 cause the complex to be electrostatically neutral (¶ bridging pg 21-22)" (Ans. 7). *See Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985) ("It is also an elementary principle of patent law that when, as by a recitation of ranges or

otherwise, a claim covers several compositions, the claim is 'anticipated' if *one* of them is in the prior art.")

Claims 35 and 41

Appellants argue that Behr does not teach that the "further step of receptor stimulation, tissue injury or cell injury might activate antigen presenting cells and therefore enhance a (disclosed in the Behr reference to be an undesired) immune response (Claim 35)" (App. Br. 20-21). Appellants argue that Behr does not teach that "Langerhans cells can be targeted using the claimed method and materials (Claim 41)" (*id.* at 21).

The Examiner responds that "[c]laims 35 and 41 are included because administering the complex to the skin/mucosa as taught by Behr inherently would activate APCs by toxin activation" (Ans. 7).

We find that the Examiner has made a reasonable argument based upon the evidence of Liu that administration of an antigen would activate antigen presenting cells, including Langerhans cells found in the epidermis (FF 10-13). Appellants have provided no evidence to rebut this position. *See In re Best*, 562 F.2d at 1255.

Claim 40

Appellants argue that Behr does not teach "that a plasmid DNA can be successfully used in the claimed method" (App. Br. 21).

We are not persuaded because Behr teaches the use of plasmid DNA throughout its Examples, for example, in the transfection in Example 14 (FF 6), where Behr states that "the compositions enable the plasmid to be transferred efficiently into the brain of mice" (Behr, col. 13, ll. 7-8).

Conclusions of Law

The evidence of record supports the Examiner's conclusion that Behr, as evidenced by Liu, Mittal, and Kuby, anticipates claims 23, 28, 35, 40, 41, and 44.

The evidence of record does not support the Examiner's conclusion that Behr, as evidenced by Liu, Mittal, and Kuby, anticipates claims 24-26, 30-32, and 43.

C. 35 U.S.C. § 103(a) over Behr, Liu, Mittal, Kuby, and Holler

We have already found that Behr anticipates the method of claims 23, 28, 35, 40, 41, and 44. Anticipation is the epitome of obviousness. *In re McDaniel*, 293 F.3d 1379, 1385-1386 (Fed. Cir. 2002). Therefore, we affirm the § 103 rejection of claims 23, 28, 35, 40, 41, and 44.

The Examiner provides no reason why claims 24-26, 30-32, and 43 would have been obvious. Therefore, we reverse the § 103 rejection of claims 24-26, 30-32, and 43. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.")

SUMMARY

In summary[2], we reverse the rejection of claim 30 under 35 U.S.C. § 112, second paragraph as being indefinite.

[2] We note that claims 33 and 42 were not subject to any rejection on appeal.

We affirm the rejections of claims 23, 28, 35, 40, 41, and 44 under 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a).

We reverse the rejections of claims 24-26, 30-32, and 43 under 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a).

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED-IN-PART

McCOLLUM, *Administrative Patent Judge*, dissenting-in-part.

I concur with the decision to reverse the rejection of claim 30 under 35 U.S.C. § 112, second paragraph, affirm the rejections of claims 23, 28, 35, 40, 41, and 44 under 35 U.S.C. §§ 102(e) and 103(a), and reverse the rejections of claims 24-26 and 30-32 under 35 U.S.C. §§ 102(e) and 103(a). However, I disagree with the decision to reverse the rejections of claim 43 under 35 U.S.C. §§ 102(e) and 103(a).

Claim 23 is directed to a method comprising "selecting a gene delivery complex . . . comprising DNA and a sugar, or polyethylenimine, or polyethylenimine derivative." Claim 43 depends from claim 23 and recites that "the derivative is a sugar-modified polyethylenimine."

The majority interprets claim 43 to require that the complex contain a sugar-modified polyethylenimine. I do not agree.

Claim 23 requires that the complex contain a sugar, polyethylenimine, *or* a polyethylenimine derivative. Claim 43 requires that the polyethylenimine derivative is a sugar-modified polyethylenimine. Claim 43 does not explicitly state that the complex comprises the polyethylenimine derivative. Therefore, I do not agree that the language in claim 43 cannot reasonably be interpreted to require that the complex comprise a sugar, polyethylenimine, *or* a sugar-modified polyethylenimine. Thus, giving claim 43 its broadest reasonable interpretation, I agree with the Examiner that claim 43 "encompass[es] non-

sugar-modified PEI . . . as in parent claim [23]" (Ans. 7).[3] The majority finds, and I agree, that Behr discloses a complex containing PEI (FF 7). Thus, I would affirm the rejections of claim 43 for the reasons we are affirming the rejections of claim 23.

DISSENTING-IN-PART

cdc

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[3] The Examiner rejects claims 25 and 26 on the same basis (Ans. 7). However, unlike claim 43, claims 25 and 26 depend from claim 24, which recites that the "complex comprises DNA and glucose or a polyethylenimine derivative." Thus, unlike claim 43, claims 25 and 26 require that the complex contains glucose or a polyethylenimine derivative. Thus, I agree with the majority's decision to reverse the rejections of claims 25 and 26.